



Department of Veterans Affairs
Northern California Health Care System

RESEARCH SERVICE

CONDUCTING RESEARCH VISITS IN NON-VA LOCATIONS

Research Service Standard Operating Procedures (SOP)

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1. PURPOSE

The purpose of this SOP is to define general guidelines for the conduct of research visits with Veteran or non-Veteran research subjects in non-VA locations including but not limited to 1) the research subject's home, 2) another residential setting, 3) a hotel/motel or 4) shopping mall.

The following locations are not subject to the requirements of this SOP as these locations are likely to pose little if any more risk to staff than VA facilities:

- A. Institutions with an academic affiliation with the VA, such as UC Davis, UC Berkeley, UCSF, California Northstate University, etc.
- B. Facilities contracted or have an established agreement with the VA to provide care or services to VA patients, such as inpatient/outpatient clinics, dialysis centers, laboratories, imaging centers, long-term care facilities, etc.

2. SCOPE

All VANCHCS research conducted at non-VANCHCS locations must be approved in accordance with established guidelines and must be directed by a PI.

3. RESPONSIBILITY

- A. The PI desiring to conduct research visits at non-VA locations is responsible for
 - 1. securing supervisor approval for such visits and documenting this approval on the Scope of Research Practice;
 - 2. following this SOP in seeking approval in accordance with established guidelines for IRB and R&DC approval of VANCHCS research;
 - 3. ensuring that all research team members proposed to complete research visits in non-VA locations complete training equivalent to that completed by home-based primary care providers to include completing TMS training for prevention and management of disruptive behavior (levels I, II, and III) and annual in-service training by VA police (contact the Research Service for assistance with this training);
 - 4. completing training equivalent to that completed by home-based primary care providers as listed in item 3. immediately above;
 - 5. addressing in their research protocol the type of information that is needed to assess the safety of the non-VA environment in which research visits are proposed to occur.
- B. The VANCHCS IRB, in the course of reviewing research protocols including completion of research visits at non-VA locations, is charged with ensuring that all IRB approval criteria are met.
- C. The VANCHCS Research Service is responsible for ensuring that the requirement for completing specialized training as indicated in A.1 is met by the following personnel for

research protocols including research visits at non-VA locations:

1. The PI
2. All research team members who will complete visits in non-VA locations

4. **PROCEDURES**

Research protocols that request to conduct visits with Veteran research subjects at non-VA locations are expected to include the following procedures/specifications in the research protocol and in the information submitted for consideration by the IRB of record for the research protocol:

- A. All subject research visits to be completed at non-VA locations should be completed during the regular tour of duty of the (paid or WOC) VA employee completing the visit.
- B. Whenever possible, the travel to and from the non-VA location in which the research visit is completed should be completed in a government vehicle.
- C. The completion of research visits in the non-VA location such as the research subject's homes shall be described in the research protocol and approved by the IRB of record.
Note: VA employees who operate within their Scope of Practice are generally covered by VA tort coverage.
- D. Consent for completion of research visits at a non-VA location such as in the subject's home must be obtained from research subjects prior to completing research visits in non-VA locations.
- E. Dates and times of research visits to be completed in the non-VA location such as the subject's home must be arranged in advance, confirmed in advance, and the convenience of the research visit further confirmed at the time of arrival of the researcher at the non-VA location such as the subject's home.
- F. Other considerations dependent on the specific non-VA location and the context of the protocol. These could include a communication plan and other plans/processes for minimizing potential hazards of the non-VA location in which research visits are proposed as applicable. Some issues that the PI might wish to consider and address as appropriate include but are not limited to the following:
 1. Does the location or environment of the proposed non-VA location pose any physical, biological, chemical, or infection hazards, and if so, what actions can research staff take to minimize physical hazards to themselves and research subjects?
 2. What is the likelihood that the researcher might encounter armed, aggressive, or otherwise potentially dangerous individuals or aggressive animals in the proposed non-VA location, and what actions are proposed to minimize risk to researchers?
 3. Would it be appropriate to implement as policy within the protocol a detailed communication plan involving notification of the PI/supervisor when the

researcher completing research visits in non-VA locations a) departs for the non-VA location, b) arrives on site, and c) has completed the visit and is departing, together with an action plan to be followed if researchers do not return from the non-VA location when expected?

5. REFERENCES

38 CFR 16 (VA) "Protection of Human Subjects"
45 CFR 46 (HSS) "Protection of Human Subjects"
21 CFR 50 (FDA) "Protection of Human Subjects"
21 CFR 56 (FDA) "Institutional Review Boards"
VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects"
VHA Handbook 1200.8, "Safety of Personnel Engaged in Research"
VA Northern California Health Care System Home-Based Primary Care SOP 1-1 "Home-Based Primary Care Patient and Caregiver Home Safety and Risk Assessment Standard Operating Procedure"
VA Northern California Health Care System Form 612/HBPC 11C-3 "Patient Rights and Responsibilities"
VA Northern California Health Care System Home-Based Primary Care SOP 1-2 "Home-Based Primary Care Employee Safety Standard Operating Procedure"

6. SIGNATURE BLOCK



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